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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,126	02/27/2006	Mark Jozef Albert Waer	50571/003001	3050
21559	7590	07/21/2008		
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			EXAMINER YOUNG, SHAWQUITA	
			ART UNIT 1626	PAPER NUMBER
			NOTIFICATION DATE 07/21/2008	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Office Action Summary

Application No.

10/595,126

Applicant(s)

WAER ET AL.

Examiner

SHAWQUIA YOUNG

Art Unit

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-17 and 19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-17 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 February 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 13-17 and 19 are currently pending in the instant application.

I. *Response to Arguments/Remarks*

Applicants' arguments and remarks, filed on April 22, 2008, in reference to the rejection of claim 13 is rejected under 103 (a) as being unpatentable over Matter, et al. and the rejection of claims 13-17 and 19 under 35 USC 103(a) as being unpatentable over Waer, et al. (US 7,276,506) have been considered but are partially persuasive.

Applicants have amended the claims by deleting the following compounds: 2-amino-4-morpholino-6-(4-propoxyphenyl) pteridine, 2-amino-4-morpholino-6-(4-butoxyphenyl) pteridine, 2-amino-4-(4-methyl-piperidine)-6-[[3,4-dimethoxyphenyl]]pteridine, 2-amino-4-((R)-sec-butylamine)-6-[[3,4-(dimethoxyphenyl)]]pteridine and 2-amino-4-((S)-sec-butylamine)-6-[[3,4-(dimethoxyphenyl)]]pteridine. Thus the part of the rejection that pertains to the deleted compounds has been withdrawn.

However, Applicants' arguments traversing the rejections of claim 13 as being unpatentable over Matter, et al. and Waer, et al. with regards to the compound 2-amino-4-morpholino-6-(4-ethoxyphenyl) pteridine have been maintained. Applicants argue that the claimed compound 2-amino-4-morpholino-6-(4-ethoxyphenyl) pteridine has an IC_{50} of 3.7 $\mu\text{mol/L}$ in the MLR assay whereas the prior art compound 2-amino-4-morpholino-6-(4-methoxyphenyl) pteridine in Waer, et al. (7,276,506) has an IC_{50} of 15 $\mu\text{mol/L}$ in the MLR assay. Applicants' arguments merely containing comparison data

between the claimed invention and the prior art is not sufficient in overcoming the 103 rejections. The Examiner wants to point out that yes the ethoxy compound is more effective when compared to the methoxy compound but both compounds are still effective. The Examiner does not consider the difference in the IC₅₀ data of the two compounds to be unexpected results. The Examiner wants to further state that one of ordinary skill in the art would expect that since the methoxy compound is effective in the MLR assay than the ethoxy compound would be effective in the same type of assay. This is supported by the actual data Applicants' supplied in the arguments. Thus the Examiner has **maintained** the rejections and the Office Action is final.

II. ***Rejection(s)***

35 USC § 103 - OBVIOUSNESS REJECTION

The following is a quotation of 35 U.S.C. § 103(a) that forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Graham v. John Deere Co. set forth the factual inquiries necessary to determine

obviousness under 35 U.S.C. §103(a). See *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). Specifically, the analysis must employ the following factual inquiries:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

(1) Claim 13 is rejected under 35 U.S.C. § 103(a) as being unpatentable over *Matter, et al.* Applicants claim a pteridine derivative selected from the group consisting of various species that include 2-amino-4-morpholino-6-(4-ethoxyphenyl)pteridine.

The Scope and Content of the Prior Art (MPEP §2141.01)

The *Matter, et al.* reference teaches 4-amino-pteridine compounds as nitric oxide synthase inhibitors that include 2-amino-4-morpholino-6-(4-methoxyphenyl)pteridine (See ID 313 on page 2925).

The Difference Between the Prior Art and the Claims (MPEP §2141.02)

The difference between the prior art of *Matter, et al.* and the instant invention is that the applicants are claiming a derivative with an alkoxy substituent (ethoxy) attached to the phenyl ring in the 6-position of the pteridine core and the prior art has a similar derivative with a methoxy substituent.

Prima Facie Obviousness-The Rational and Motivation (MPEP §2142-2413)

In *In re Henze*, 85 U.S.P.Q. 261,263 (C.C.P.A. 1950), it was well established that

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adjacent homologs are considered to be obvious absent unexpected results. A pteridine derivative with a methoxy substituent attached to the phenyl ring in the 6-position of the pteridine core was already known in the prior art and simply changing the substituent to other alkoxy groups is obvious and will lead to a reasonable expectation of success. Therefore, one of ordinary skill in the art would have been motivated to prepare the instantly claimed species of 2-amino-4-morpholino-6-(4-ethoxyphenyl)pteridine.

(2) Claims 13-17 and 19 are rejected under 35 U.S.C. § 103(a) as being unpatentable over *Waer, et al.* (US Patent No. 7,276,506). Applicants claim a pteridine derivative selected from the group consisting of various species that include 2-amino-4-morpholino-6-(4-ethoxyphenyl)pteridine.

The Scope and Content of the Prior Art (MPEP §2141.01)

The *Waer, et al.* reference teaches pteridine derivatives with immunosuppressive effects that includes 2-amino-4-morpholino-6-(4-methoxyphenyl)pteridine (See example 23.

The Difference Between the Prior Art and the Claims (MPEP §2141.02)

The difference between the prior art of Waer, *et al.* and the instant invention is that the applicants are claiming derivatives with an alkoxy substituent (ethoxy) attached to the phenyl ring in the 6-position of the pteridine core ring instead of methoxy group.

Prima Facie Obviousness-The Rational and Motivation (MPEP §2142-2413)

In In re Henze, 85 U.S.P.Q. 261,263 (C.C.P.A. 1950), it was well established that adjacent homologs are considered to be obvious absent unexpected results. A pteridine derivative with a methoxy substituent attached to the phenyl ring in the 6-position of the pteridine core was already known in the prior art and simply changing the substituent to other alkoxy groups is obvious and will lead to a reasonable expectation of success. Therefore, one of ordinary skill in the art would have been motivated to prepare the instantly claimed species of 2-amino-4-morpholino-6-(4-ethoxyphenyl)pteridine since the prior art teaches 2-amino-4-morpholino-6-(4-methoxyphenyl)pteridine and furthers teaches that the phenyl ring can be substituted with a C₁-C₇ alkoxy group.

III. Conclusion

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shawquia Young/

Examiner, Art Unit 1626

/Kamal A Saeed, Ph.D./

Primary Examiner, Art Unit 1626

